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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/787,334

Applicant(s)

CHEMTOB ET AL.

Examin r

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspond nc address --

**Peri d f r Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Sequence Comparison*.

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. Amendment C, filed 8/20/03, has been entered into the record.
- B. Amendment B, filed 7/09/03, has been entered into the record.
- C. Claims 1-7 and 10 are pending in this application. Claims 6 and 7 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 1-5 and 10 are the subject of this Office Action.
- D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Specification***

- A. The objection to the specification has been withdrawn since Applicants have provided accurate priority information regarding PCT/CA99/00844.

### ***3. Claim Objections***

- A. Claim 5 is objected to since the syntax could be improved by adding the phrase “or a” before “mixture.”

### ***4. Claim Rejections - 35 USC § 112, first paragraph – new matter***

- A. Claim 2 will not be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. As suggested by the Examiner, Applicants have amended claim 2 to recite “88% homology. Although the Examiner is not able to find literal support for this limitation, it is clear, given the previous version of claim 2, which recites “75% homologus” that Applicants have support for this new limitation. SEQ ID NO:1, 4-8 and 10-11 are 8 residues in length. Therefore, “75% homology” was clear. However, since SEQ ID NO:9 only contains 7 residues, “75% homology” to 7 residues was unclear. Since it was clear that Applicants intended claim 2 to encompass at least one amino acid change, then it can be concluded that 88%, which is approximately one amino acid change in the 7 residues of SEQ ID NO:9, has support. If anything, this amendment further limits the scope of claim 2.

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B. Claims 3, 4 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting contractions of bovine and porcine uterine muscle in vitro, does not reasonably provide enablement for a method of inhibiting uterine contractions in humans, or for inhibiting dysmenorrhea or premature delivery of a fetus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants have demonstrated in the specification (Examples IV and V) that PCP's inhibit uterine contraction test strips in vitro. However, the breadth of the claims is excessive with regard to Applicants claiming a method of inhibiting uterine contractions in humans, or for inhibiting dysmenorrhea or premature delivery of a fetus. Applicants have not provided a nexus demonstrating that this in vitro procedure in test strips is effective in vivo in humans. Therefore, it is not clear if this is an art-accepted model with regard to reducing the occurrence of dysmennorrhea (which is simply meant to mean pain during uterine contractions) or for reducing the occurrence of premature delivery of a fetus. Though the Examiner did suggest that Applicants amend the claims to remove the term "prevent" and to add the phrase "reduce the occurrence of," upon further review it is still not clear that Applicants are enabled for these methods. If the in vitro test is indicative (i.e. art-accepted model) of successful treatment of claims 3, 4 and 10 in vivo, then Applicants are requested to provide such evidence. As stands, it is not predictable to the artisan that the prostaglandin receptor antagonists would be effective in vivo.

Therefore, in summary, the breadth of the claims is excessive regarding reducing the occurrence of premature delivery of a fetus, dysmenorrheal, or uterine contractions in vivo in humans. Applicants have provided no guidance or working examples of in vivo use, or success, of the claimed compounds. Therefore, it is not predictable to the artisan how to use the present invention. For these reasons, the Examiner concludes that undue experimentation is required to practice the claimed invention.

### ***5. Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Abramovitz et al. (WO 95/00551 – on the IDS of 6/18/01). The claim recites a PGF2 receptor antagonist consisting essentially of SEQ ID NO:1 or 4-11. Abramovitz et al. teach a PGF2 receptor comprising at least SEQ ID

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NO:1 of the present invention (Sequence Comparison). The phrase "consisting essentially of" reads on the full-length receptor. The use of the full-length PGF2 receptor of Abramovitz would act as an antagonist since the use of this protein would bind excess agonist in the body, thereby acting as an antagonist to the endogenous PGF2 receptor. Abramovitz et al. also teach pharmaceutical compositions (the buffers used in Example 7). The artisan would immediately envision the protein in a pharmaceutical composition such as buffer or water. The Examiner realizes that it as suggested to Applicants to recite the phrase "consisting essentially of." However, upon further review, it was concluded that this phrase still allows for reading on the full-length receptor. The Examiner apologizes for this suggestion.

***Advisory information***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
September 29, 2003



ROBERT LANDSMAN  
PATENT EXAMINER